

**REMARKS****Summary of Claim Amendments**

Upon entry of the response and remarks, claims 1, 3, and 8-9 are amended, claim 2 is canceled, wherein claims 1 and 3-14 remain pending. Of the pending claims, claims 1 and 6 are independent. Applicants note that the amendment to claim 1 further clarifies the claim. In addition, the amendments to claims 3 and 8 add a period to the end of the claim as suggested by the Examiner. In addition, claims 8 and 9 are amended to now depend from claim 1. Thus, support for the amendment is found in the originally filed claims and in the specification, for example, original claim 2, and page 6, lines 12-16 of the specification, and is inherent therein. Applicants submit that no new matter is added.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

**Claim of Priority**

Applicants note the present application is a National Stage Application of International Application No. PCT/JP2003/015794. Therefore, Applicants respectfully request that the Examiner acknowledge the same by checking boxes 12(a)(3) on the Office Action Summary form in the next communication from the USPTO.

**Information Disclosure Statement**

Applicants filed an Information Disclosure Statement on December 6, 2006. Therefore, in the next communication from the Office, Applicants respectfully request that the Examiner consider the documents cited in the Information Disclosure Statement by returning a completely initialed Form PTO-1449 submitted therewith.

**Response to Claim Objections**

The Office Action objects to claims 3 and 8 because the claims are missing a period at the end of the claim. In response, Applicants have amended claims 3 and 8 to add an period to the end of the claim. Therefore, Applicants respectfully request withdrawal of the claim objection.

**RESPONSE TO CLAIM REJECTIONS****1. Response to Rejection under 35 U.S.C. § 112, second paragraph**

The Office Action rejects claims 1-14 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite because the term "substantially" in claim 1 is a relative term.

In response, although Applicants believe "substantially" to be definite, Applicants have nevertheless amended claim 1 to remove "substantially" to advance the prosecution of the present application.

Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejection of claims 1-14.

**2. Response to Rejection under 35 U.S.C. § 102(b)**

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The Office Action contains the following rejections under 35 U.S.C. § 102(b):

- (a) Claims 1-14 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by TAKEUCHI (US 5,624,962);
- (b) Claims 1-14 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by PAN (US 5,912,007);
- (c) Claims 1, 3-7, 10 and 13 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by LAPIDUS (US 5,543,148);

Rejection (a) in the Office Action asserts that TAKEUCHI discloses drug compositions having the property of reversible thermosetting gelation that may be used in the oral cavity. Further, the rejection asserts that the compositions may comprise drugs including anesthetics, antihistamines and mixtures thereof. Rejection (b) in the Office Action asserts that PAN discloses drug deliver systems, which may comprise drugs including antihistamines, anesthetics and mixtures thereof. Rejection (c) in the Office Action asserts that LAPIDUS discloses delivery systems for topical application of a treatment agent, where the treatment agents can include anesthetics, antihistamines and mixtures thereof.

In response, Applicants respectfully traverse the rejection under 35 U.S.C. § 102(b). In particular, Applicants respectfully submit that the cited documents fail to disclose at least

claims 1 and 6 as presently claimed.

Applicants note that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, **in a single prior art reference.**” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). *See also* MPEP § 2131.

Regarding rejection (a), TAKEUCHI discloses a composition to be used in ophthalmology and which contains epinephrine (see, e.g., claims 2 and 3 of TAKEUCHI). However, in contrast with TAKEUCHI, the composition of claim 1 is to be used in oral surgery or dental treatment, whereas TAKEUCHI is directed to use in ophthalmology. Moreover, the composition and agent of claims 1 and 6, respectively, **specifically exclude catecholamine** (of which epinephrine is a species of the genus catecholamine). Therefore, the claims cannot be rejected under 35 U.S.C. § 102 because every element of claims 1 or 6 are not disclosed by TAKEUCHI.

Regarding rejection (b), PAN discloses a drug delivery system composition containing ionic polysaccharide and a cross-linking agent (Al, Ca, Cu, Fe, Mg and the like) (*see, e.g.*, col. 5, line 58 – col. 6, line 10, col. 7, lines 32-42). However, in contrast with PAN, the composition of claim 1 and agent of claim 6 are intended to exclude a **polysaccharide or a cross-linking agent**, in view of the language “aqueous solution,” in claim 1, and the “consisting of” language in claim 6. Thus, the present claims are different from PAN in that they would exclude at least the ionic polysaccharide and a cross-linking agent as disclosed by

PAN. Therefore, the claims cannot be rejected under 35 U.S.C. § 102 because every element of claims 1 or 6 are not disclosed by PAN.

Regarding rejection (c), LAPIDUS discloses a drug delivery system composition for topical application in the form of a gel (*see, e.g.,* Abstract). However, in contrast with LAOIDUS, at least the composition of claim 1 is directed to an **aqueous solution** for use in **oral surgery or dental treatment**. Moreover, the agent of claim 6 includes “consisting of” language which would exclude certain ingredients of LAPIDUS, e.g., gelling agents (*see, e.g.,* col. 4, lines 3-24). Thus, the claims cannot be rejected under 35 U.S.C. § 102 because every element of claims 1 or 6 are not disclosed by LAPIDUS.

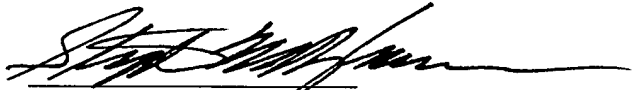
Accordingly, since the single cited document of TAKEUCHI, PAN, or LAPIDUS do not provide all the elements of the claimed invention, withdrawal of the current rejections under 35 U.S.C. § 102(b) is respectfully requested.

### CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the objection and rejections of record and allow the pending claims. Allowance of the application is requested, with an early mailing of the Notice of Allowance and Allowability.

If the Examiner has any questions or wishes to further discuss this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,  
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